UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

BEVERLY R. MAXWELL,
Plaintiff,

v.

HOWMEDICA OSTEONICS CORP. and STRYKER CORPORATION,
Defendant.

Civil Action No.: 5:07-cv-1062 (GTS)(DEP)

PLAINTIFF'S STATEMENT OF MATERIAL FACTS

Plaintiff, Beverly R. Maxwell ("Plaintiff") respectfully submits this Statement of Material Facts in opposition of Defendant's Motion for Summary Judgment dismissing Plaintiff's Complaint in its entirety.

The Incident

1. On June 15, 2004, Plaintiff underwent a total knee replacement procedure at Oswego Hospital in Oswego, New York. *See Defendants* ***Statement*** *of Material Fact,* Exhibit "A", Complaint at 19. The procedure was performed by Dr. William Mahon, an orthopedic surgeon. *Ref. Defendant's* ***Statement*** *of Material Fact; Exhibit "B", Operative Report.*

2. Prior to undergoing the knee replacement procedure, Plaintiff advised Dr. Mahon of a foreign body sensitivity, specifically, allergic reaction to "cheap jewelry." ***See Exhibit*** *"C",* ***Plaint*** ***s*** *Deposition* ***Transcript*** *at 80.*

The Product

3. According to product labels contained in Plaintiffs surgical records, the product implanted into Plaintiff was the Duracon Total Knee System ("Duracon System"), manufactured by HOC. ***See*** *Defendant'* ***Statement of*** *Material Fact;* ***Exhibit "D", product labels.***

4. The product labels reveal that the following metal components were implanted into Plaintiff:

- Howmedica Cemented Stem Extender (Cat# 6476-8-250; Lot# LCM123)

- Duracon Non-Beaded Femoral Component (Cat#6630-0-515; Lot# LTTLK)

- Howmedica Universal Tibial Baseplate (Cat# 6632-3-620; Lot# NOKF)

See Exhibit "E", HOC Intetrogatoy ***Responses, pp.*** *2, 3.* HOC's Interrogatory Responses were certified by William Cymbaluk, HOC's Vice President, Clinical, Quality and Regulatory Affairs.

5. The Duracon System is an FDA-regulated medical device which can be sold only to licensed health care providers and must be prescribed for use by a licensed surgeon based upon his or her education, training and experience, and based upon his or her medical judgment and assessment of the patient's specific needs. As such potential risks, warnings, indications and contraindications, and potential adverse events are provided to the physician as a learned intermediary. Through the learned intermediary, the patient should be advised of the risks, benefits, indications, contraindications and potential adverse events in connection with use of the device. ***See Defendant's Response Nos.*** *7, 21.*

6. The risks and warnings regarding use of the device are set forth in materials such as the product labels, package inserts and surgical protocols, were provided to or made available to Plaintiffs physician, Dr. **Mahon.** ***See Defendant's Response*** *Nor.17, 21.*

7. The package inserts for the subject device components distributed with the components themselves contained specific information regarding the metallic composition of the components. Each component package insert provided, in pertinent part:

> The metallic components (the femoral component, tibial and patellar baseplates, sintered beads, wedges and spacers) are manufactured from cast cobalt-chromium-molybdenum alloy (Vitallium ® Alloy) conforming to ASTM standard F75. The screws and stem extenders are manufactured from wrought

cobalt-chromium-molybdenum alloy (Vitallium 8 Alloy) conforming to ASTM standard F1537. The polyethylene components are manufactured from ultra-high-molecular-weight polyethylene (UHMWPE) conforming to ASTM standard F648.

See *Exhibit "F", HOC's Initial Disclosures* ***containing*** *Package Inserts at HOC 00004; Ref Exhibit "E", HOC's Interrogatory* ***Responses*** *at ¶ 15.*

Dated: September 9, 2009
At: Oswego, New York

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